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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,495	01/20/2006	Elliott A Gruskin	127304.00901	6177

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PEPPER HAMILTON LLP
ONE MELLON CENTER, 50TH FLOOR
500 GRANT STREET
PITTSBURGH, PA 15219

EXAMINER

PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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10/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,495	Applicant(s) GRUSKIN ET AL.	
	Examiner Rebecca E. Prouty	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 4,6-8,12-21,23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,9-11 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/07, 4/06</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicant's election without traverse of Group 24, Claims 1-3, 5, 9-11, and 22 drawn to a chimeric protein comprising chondroitinase ABC exolyase and neurotrophic factors in the reply filed on 8/28/08 is acknowledged. Applicants remarks that some claims (i.e., claim 1) are linking claims among groups 1-168 is noted. The examiner expressly confirms that claim 1 links inventions 1-168. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 1. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim,

such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 4, 6-8, 12-21 and 23-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/28/08.

Claims 5 and 9 are objected to because of the following informalities:

- abbreviations should not be used in the claims without first setting forth the full text for which they are used.
- N-CAM appears twice in the list of claim 5
- TGF \square and \square in claim 9 should presumably be TGF α and β

appropriate correction is required.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

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distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is confusing in the recitation of "wherein the peptide linkage is an Fc portion of an immunoglobulin" as it is unclear how a peptide linkage (i.e., peptide bond) can be a peptide itself. It is assumed that applicants in fact intended claims 10 and 11 to recite not a peptide linkage but a peptide linker.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, 9, 10 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al. (WO 00/64482) in view of either of Yick et al. (reference C1 of applicants IDS of 7/07) or Zuo et al. (reference CAG of applicants IDS of 4/06)

Olsen et al. teach a chimeric protein composed of two portions a first component capable of suppressing or neutralizing a neurite growth inhibitory molecule and a second component capable of stimulating neurite growth and/or regeneration. (see page 4) and pharmaceutical compositions thereof. Olsen et al. specifically teach that the component capable of stimulating neurite growth and/or regeneration can be a neurotrophic molecule including NGF, BDNF, NT3, FGF and many others (see page 10). Olsen et al. further teach that the neurite growth inhibitory molecule which is inhibited or suppressed by the first component of the chimeric molecule includes chondroitin proteoglycans (see page 25). Olsen et al. further teach that the two components of the chimeric molecule may be optionally separated by a peptide linker (see page 8). Olsen et al. do not explicitly teach that the component capable of suppressing or neutralizing a neurite growth inhibitory molecule is a polypeptide possessing matrix modification activity or particularly a chondroitinase such as chondroitinase ABC.

Each of Yick et al. and Zuo et al. teach that chondroitin proteoglycans are extracellular matrix components which inhibit neuronal growth and regeneration following injury and that the

administration of chondroitinase ABC which degrades chondroitin proteoglycans promotes axonal regeneration.

Therefore, it would have been obvious to one of ordinary skill in the art to select chondroitinase ABC as the component capable of suppressing or neutralizing a neurite growth inhibitory molecule in the chimeric molecule of Olsen et al. as the disclosures of Yick et al. and Zuo et al. show that chondroitinase ABC has all the properties that are preferred in this component as disclosed by Olsen et al.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al. (WO 00/64482) in view of either of Yick et al. or Zuo et al. as applied to claims 1-3, 5, 9, 10 and 22 above, and further in view of Gearing (US Patent 5,262,522).

Olsen et al., Yick et al. and Zuo et al. are discussed above but do not explicitly disclose the use of an immunoglobulin Fc portion as the peptide linker between the two portions of the chimeric protein.

Gearing et al. teach a chimeric protein having two separate polypeptide domains optionally separated by a peptide linker. Gearing et al. teach that a preferred peptide linker is an immunoglobulin Fc portion (see column 8, lines 17-43).

Therefore, it would have been obvious to one of ordinary skill in the art to select an immunoglobulin Fc portion as the peptide linker of the chimeric molecule of Olson et al. as Gearing et al. specifically teach this as a preferred linker molecule for another chimeric protein formed by the conjugation of two proteins which don't naturally occur together.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652